

Dear Dr. William S. Stokes:

I am grateful to learn that NIEHS is asking for public comments on the use of non-animal (in vitro cell culture) methods to study the toxic effects of chemicals from acute (short-term) exposure. I am aware that since the 1920s, scientists have studied acute toxicity using lethal poisoning tests in which animals are force-fed, injected with, or forced to inhale a chemical until they die. These tests are not only cruel, they are virtually irrelevant to humans (producing inaccurate and misleading results in almost half of all cases, whereas the non-animal cell culture tests have been found to be highly predictive of chemical toxicity in humans). While non-animal test methods are required to undergo rigorous scientific scrutiny ("validation") before they can be used, unbelievably animal tests have never been proved to be scientifically reliable, reproducible, or relevant to humans. In fact, one top scientist at the NIEHS workshop even stated that the results of lethal poisoning tests on rats aren't even relevant to rats, let alone to people! Yet the government wants this double standard to stay in place and continues to demand a far higher level of performance from non-animal tests.

One form of lethal dose testing, the notorious LD50, is slowly being phased out internationally. However, it is being replaced with other animal-poisoning tests that use fewer animals but which still cause extreme suffering and death for the animals used. While the in vitro cell culture tests can-and should-be used to replace all lethal animal-poisoning tests, the government is only proposing to use the non-animal method to set a "starting dose" for the lethal poisoning tests rather than as a complete replacement for the animal tests. It is therefore my belief that:

1. NIEHS should adopt the new non-animal test methods IMMEDIATELY. The non-animal test methods have been considered for almost 20 years, and animals should not continue to suffer and die because of bureaucratic inertia.
2. NIEHS recommends using the non-animal method to set the starting dose for further animal- poisoning tests. While this may reduce the number of animals killed in acute poisoning studies, it does not go far enough. Government agencies should use in vitro cell culture tests to COMPLETELY REPLACE the use of animals in lethal dose tests.
3. At a minimum, ALL government agencies that currently require the acute animal-poisoning studies should IMMEDIATELY incorporate the in vitro cell culture method as a transitional means of reducing the number of animals killed and should fully support the use of this method as an eventual REPLACEMENT for lethal-dose poisoning studies. In particular, the EPA must immediately incorporate the non-animal cell culture method into its HPV chemical program, as promised in its October 1999 agreement with the animal protection community.

I appreciate the opportunity to express my views.

Sincerely,
Annette Swartz